



DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration  
Rockville MD 20857

DEC 22 2004

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John M. Baldoni, Ph.D.  
David M. Cocchetto, Ph.D.  
GlaxoSmithKline Research and Development  
P.O. Box 13398  
Research Triangle Park, NC 27709-3398

Re: Docket No. 2004P-0290/CP1

Dear Drs. Baldoni and Cocchetto:

I am writing to inform you that the Food and Drug Administration (FDA) has not yet resolved the issues raised in your petition dated July 7, 2004, requesting that FDA refrain from approving any ANDA for topical mupirocin calcium products containing the amorphous form of the active ingredient.

FDA has been unable to reach a decision on your petition because it raises issues that require additional review and analysis by the Agency. This interim response is provided in accordance with FDA regulations on citizen petitions (21 CFR 10.30(e)(2)). We will respond to your petition as soon as we have reached a decision on your request.

Sincerely,

Jane A. Axelrad  
Associate Director for Policy  
Center for Drug Evaluation and Research

2004P-0290

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